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## BACKGROUND OF THE INVENTION

Preservation of blood, cellular biological substances, tissue and other thermolabile products frequently involves product maintenance at extremely cold temperatures. Cellular biological substances are the fundamental, structural and functional unit of living organisms. Thermolabile substances are those substances which are easily altered or decomposed by heat. One economical mode for containment involves the use of encapsulating plastic since plastic is relatively inexpensive and lends itself to mass production techniques. However, many plastics suffer from brittleness at extremely low cryogenic temperatures and seams are sometimes susceptible to fracture.

In addition, bags that are formed either by folding over a planar material and seaming along peripheries or layering two planar materials and seaming along the peripheries have a generally ovoid shape when filled with a liquid. This is because the cross-sectional area adjacent either the fold or the seam has an area of decreasing cross-sectional width as it tapers from the center. While for many applications, this type of narrowing is unobjectionable, for certain biological fluids such as white stem cells, a bag having non-uniform thickness along its cross-section may impair the integrity of the biological product, particularly during temperature changes. One reason for quality loss during a change in temperature may involve the differential thermal gradient within the thermolabile or cellular substance caused by variations in thickness induced by the geometric shape of the bag itself. Stated alternatively, the center portion of the bag is thicker than the edges.

A corollary to the above-enunciated problem entails the fact that the prior art bags, with their thicker center portions, also provides a non-planar surface on opposing sides of the bag. This results in a "high spot" which also makes uniform temperature alteration of the contents difficult especially when heat exchange is attempted by contact with a substantially planar surface that provides the heat gradient. Because the bag has

a high area, uniform contact along the entire cross-section of the surface will have been precluded.

Figure 8 reflects prior art bag structure and highlights the inherent problems associated therewith. The radio frequency seam S is thinner than the non-seamed plastic forming the bag and has its weakest point W at an edge of the seal closest to the interior I. When the product P begins to freeze, the product freezes first at the thinnest part of the bag, i.e. at edge E. Freezing proceeds inwardly, from the outside in, until an unfrozen core C exists. As the core C freezes, it expands and generates forces F which collimate and focus on the edge E because of the geometrical configuration of the bag. The force F frequently causes bag rupture at the weakest point W because the wedging force appearing at edge E tries to separate the seam with a turning moment M. Recall the bag material tends to become brittle at low temperatures, exacerbating this problem.

Figure 13 reveals a further site of prior art bag weakness. When an access port tube T is to be fitted to the bag, two horseshoe-shaped RF horns H close on the plastic membrane around the tube T and then the membrane at the seal area S. This causes another weakened area W where bag failures commonly occur.

## SUMMARY OF THE INVENTION

The instant invention addresses all of the difficulties noted hereinabove. One manifestation of the problems solved includes the formation of peripheral seams circumscribing the bag which are appreciably stronger than prior art seam structures. Preferably, the bag is formed from two symmetrical sections, each vacuum formed to provide a major wall flanked by a radiused end wall section and circumscribed by a peripheral flange. It is contemplated in one form of the invention that two half portions defining a plane of symmetry are thus formed and adhered together so that the peripheral flanges are in mating registry and sealed such as by means of adhesive, ultrasonic, R.F. welding or other means. The increased surface area of the peripheral seam flange coupled with the radiused end wall interposed between the seam flange and the major wall of the bag dissipate forces which in prior art bags could have lent themselves to rupture at the seam area.

By vacuum forming the two halves, the contour of the side wall can be carefully controlled to make them substantially planar. Thus, when the two halves are united, a container having substantially uniform cross-section substantially along the entire extent will have been provided. This geometry encourages uniform thawing, freezing and imperviousness to the stresses that attend the seams and the radiused end wall at cryogenic temperatures. This geometry also provides space efficient storage and reduced heat invasion from a warmer ambient medium when the plurality of bags are placed with their planar surfaces in contact with each other.

## OBJECTS OF THE INVENTION

Accordingly, it is an object of the present invention to provide a useful and novel bag for containing thermolabile or live cell products, a method for making same and an apparatus associated with the formation of the bag.

A further object of the present invention is to provide a device as characterized above in which the seams associated therewith have greater strength to improve the integrity of the bag.

A further object of the present invention is to provide a device as characterized above in which the major surfaces of the bag are closely spaced, parallel and substantially planar thereby increasing the likelihood that heat transfer along those planar surfaces will more uniformly alter the temperature profile of the contents within the bag.

A further object of the present invention is to provide a device as characterized above which lends itself to mass production techniques, is extremely safe to use and is durable in construction.

A further object of the present invention is to provide a device as characterized above which is substantially rectangular so as to allow the device to be stacked side by side and end to end with minimal wasted space thereby achieving space efficient storage at low temperatures which results in a reduced operating cost.

A further object of the present invention is to provide a device as characterized above which has two parallel planar surfaces which make up a high percentage of the total exterior surface of the container such that when two or more such containers, lowered to subzero temperatures, are placed in contact with each other along these large planar surfaces, the percentage of the total surface area of the combined containers available to absorb heat from a surrounding warmer medium is substantially reduced.

Viewed from a first vantage point, it is an object of the present invention to provide a bag comprising, in combination: a first bag portion having a substantially planar outer wall, a radiused edge wall circumscribing the planar outer wall and

peripheral flashing circumscribing the radiused edge wall, a second bag portion sealed to the peripheral flashing and overlying the planar outer wall of the first bag portion such that the planar outer wall is spaced from the second bag portion by a dimension at least equal to a radius of the radiused edge wall.

Viewed from a second vantage point, it is an object of the present invention to provide a method for forming a bag, the steps including: forming a first mold having a recess including a planar surface, a radiused periphery circumscribing the planar surface and a peripheral ledge circumscribing the radiused periphery and oriented parallel to the planar surface, placing a blank of sheet material over the first mold, and causing the blank to conform to the mold, removing the formed sheet and enclosing the bag.

Viewed from a third vantage point, it is an object of the present invention to provide a bag formed by: deforming a first sheet of material to have a planar outer wall, a radiused edge wall circumscribing the outer wall and peripheral flashing circumscribing the edge wall oriented parallel to the outer wall and defining a pocket, sealing the pocket with a second sheet of material.

Viewed from a fourth vantage point, it is an object of the present invention to provide a mold for forming bags comprising, in combination: a recess including a planar surface, a radiused periphery circumscribing the planar surface and a peripheral ledge circumscribing the radiused periphery and oriented parallel to the planar surface, means for receiving a blank of sheet material over the recess and lapped atop the peripheral ledge, and means for conforming the sheet material blank to a contour of the mold.

These and other objects will be made manifest when considering the following detailed specification when taken in conjunction with the appended drawing figures.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a female mold according to the present invention.

Figure 2 is a side view of one type of bag that can be formed from the mold of figure 1.

Figure 3 is a perspective view of figure 2.

Figure 4 is an end view of figure 2.

Figure 5 is an alternate to figure 4.

Figures 6(A-C) are perspective views of a first bag portion (6A), a second bag portion (6B) and the two portions placed in mating registry (6C).

Figure 7 is a perspective view of a mold plug.

Figure 8 reflects prior art bag structure and forces generated in prior art bags.

Figure 9 is a perspective view of an alternative to figures 2 through 5.

Figure 10 is a front view of figure 9.

Figure 11 is a top view of figure 10.

Figure 12 is an end view of figure 10.

Figure 13 reflects prior art technology in anchoring a port tube into a figure 8 type prior art bag.

Figure 14 reflects sealing structure and methodology for a port tube communicating through the bag according to one form of the present invention.

Figure 15 depicts the improvement over figure 8.



## DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to the drawings, wherein like reference numerals denote like parts throughout the various drawing figures, reference numeral 10 is directed to the bag according to the present invention.

In its essence, the bag is formed from a first half and a second half. Preferably each half includes a planar outer wall and a peripherally disposed radiused edge wall that terminates in peripheral flashing, the flashing oriented parallel to and spaced from the planar outer wall by the dimension of the radius. In a preferred form, each half forming the bag is a symmetrical mirror image of the other so that the overall thickness of the bag is twice the radius of either half. In another form of the invention, however, the bag can be formed as having a first half as above-described and a second half as a planar back wall overlying a recess formed by the first half and adhered to the first half by the peripheral flashing.

More particularly, the bag as shown in figures 2 through 4 include a planar outer wall 2 which terminates in a peripherally disposed edge wall 4 having a constant radius of curvature and terminating in a peripheral flashing 6 oriented substantially parallel to the planar outer wall 2. Thus, the peripheral flashing 6 is spaced from the planar outer wall 2 by the radius defining the radiused edge wall 4 and defining the recess therein.

Figure 2 further reflects an inlet tube 121 formed with a series of necked-down constrictions 123 along its length. This tube 121 can store samples of the contents of the bag 10 where each sample 125a, 125b, 125c, etc. can be sequestered from adjacent samples by sealing at the nearest constriction 123.

Figure 5 shows the version where the second half is formed from a planar sheet 8 with the first half as described for figures 2 through 4. In all embodiments, access is provided to an interior of the bag by way of at least one portal 12.

Figure 2 and figure 3 each show three portals 12 allowing communication with the interior of the bag 10. The portal is formed concurrently with the first and second

halves when the embodiment of figures 2 through 4 are to be made. The portal 12 will appear on only one half of the bag in the figure 5 embodiment. Figure 2 and figure 3 also reflect a sealed area 14 which defines an area of demarcation between a first compartment 16 and a second compartment 18 for the bag 10. Although illustrative, other compartments could be provided. The compartments 16 and 18 can be placed in fluid communication by means of a passageway 20 extending at both an upper and lower extremity of the sealed portion 14. Each passageway 20 can be subsequently heat sealed.

Typically, once the bag has been filled, the bag is massaged to urge the contents into both compartments 16 and 18. Further, the bag is manipulated to assure the segments in areas 125a, 125b, 125c, etc. are filled. Then a heat sealer can close passageways 20 (at 21) and at each constriction 123. This is desirable because once the bag is stored at cryogenic temperatures, it is preferred to minimize temperature spikes. Accordingly, a cutout 15 can appear along a central portion of sealed portion 14 so that a minimum amount of time is required to sever compartment 18 from 16. Conversely, no compartments are also contemplated as part of the invention. Please see the bag 10' of figures 9 through 12 where like parts share like numerals.

Figure 1 reflects a complementally formed female mold for allowing one half of the bag to be formed. As shown in figure 1, the female mold 30 includes a contour complementary to the bag so that the bag is a true reflection of the mold. More specifically, the planar outer wall 2 of bag 10 has its corresponding part in mold 30 as planar surface 32. Similarly, the radiused edge wall 4 of bag 10 finds its counterpart with radiused edge wall 34. Likewise, the peripheral flashing 6 finds its counterpart at the flashing support 36. In like manner, the access portals 12 are formed by portal recesses 42.

Figure 6(A-C) shows first and second bag portion halves (6A, B, respectively) and assemblage (6C) of the two halves. Alternatively, figures 6A and 6B could illustrate male mold halves over which planar blanks of plastic are draped and then deformed,

for example, under heat and/or pressure. In such a case, the outer wall 2 of the bag portions are formed by mold wall 72. Radiused edge 4 is formed with edge 74. Access portals 12 are formed via projections 82. Partition 14 finds its counterpart in mold form 84 forming <sup>two</sup> compartments defined by 86 and 88.

Figure 14 reflects structure and methodology for placing a port tube 90 into a portal 12, as shown in figure 6C. One peripheral flange 6 is sealed to the other using a complementary RF die 101 which circumscribes the compartment(s) 16 (18, etc.). Where the die 101 contacts the portal 12, the die has a corresponding arcuate portion 103. Because the plastic which formed the portal was deformed as set forth in figure 1 (or 6), the plastic has uniform thickness throughout and particularly regarding the correct tubular shape. This results in a thicker and stronger sealing - joining area, especially as compared with figure 13. As the plastic is heated and cooled both during fabrication and use, it will have been stress relieved.

Figure 7 shows a plug 57 to be received with the port tube 90 and with portal 12. The preform 57 comprises an inner first rod 53 and second concentric cylinder 55, connected by an annular top wall 51. Central to annular top wall 51 is a bore 59 extending partially into rod 53. The outer cylinder 55 is shorter than the inner rod 53.

The passageway 20 (figure 2) that allows communication between a first compartment and a second compartment 18 includes a relief area defining passageway 40 (figure 1) so that the first compartment forming recess 46 can communicate with the second compartment forming recess 48. A partition 49 constitutes the zone of demarcation between the adjacent compartments.

In fabrication, a sheet of plastic material overlies the mold 30 and the planar material is forced within the contour defined by the mold 30. This can be done by positive pressure on the side of the sheet of material opposite from the mold or it can be formed by vents V forming a vacuum within the mold cavity to draw the plastic down. The forming process can be coupled with heat and pressure and the plastics can

be formed from a family of plastics characterized by their ability to deform and retain in memory their deformed state caused by the application of heat and or pressure.

Where the figure 5 bag is to be used, a substantially planar blank of plastic is placed in overlying registry with respect to the one preformed half defined by one planar outer wall, radiused edge wall and peripheral flashing and is adhered thereto by means of adhesive, ultrasonic welding or other fastening techniques.

Preferably, however, a second mold having mirror symmetry to the figure 1 mold (as in figures 6A, B) allows a second half to be formed which is the mirror image of the first half. Thus, the peripheral flange defined by the peripheral flashing 6 is placed in overlying registry, aligning both halves (as shown in figure 6C) and then a welding technique can be used as mentioned above.

The radiused edge wall includes the advantages illustrated in figure 15. First, the planar outer wall does not have any high spots and therefore presents a substantially uniform thickness along the entire length of the bag. In addition, the radiused edge wall minimizes the existence of stress areas by dissipating focusing forces so that failure of the bag at the seam site will have been made much less likely. Finally, the peripheral flashing provides an improved purchase area for causing two halves of the bag to be united since there is an abundance of material easily accessible for adherence either by an adhesive or by welding technology.

Having thus described the invention, it should be apparent that numerous structural modifications and adaptations may be resorted to without departing from the scope and fair meaning of the instant invention as set forth hereinabove and as described hereinbelow by the claims.